

Analyzability of newly developed/commercially promoted drugs among young medical and dental doctors

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Abstract

Introduction: The development of a new chemical entity into a drug is of indispensable importance for the progression of health care. As physicians play the main and important part of any clinical trial, it is necessary to know about their awareness about clinical research, drug development, good clinical practices, and regulatory authorities.

Objective: This study was designed to assess and compare the knowledge and awareness toward drug development process among medical interns, dental interns, and postgraduates (PGs).

Methodology: This was a cross-sectional study enrolling 186 professionals of medical college and 110 professionals of dental college in Punjab who were given a prevalidated questionnaire that included 27 questions related to knowledge regarding drug development process. Data were analyzed for percentage correct responses, mean values, and intergroup comparison by applying *t*-test using SPSS version 20, IBM SPSS Statistics for Windows, Version 20.0. IBM Corp., Armonk, NY, USA.

Results: It was found that medical and dental college professionals had a very poor awareness and knowledge about drug development process to the tune of 33%. Professionals of dental college had 53.7% knowledge of clinical research in comparison to 43.2% of medical college. A statistically significant ($P < 0.05$) difference for sections on drug development, clinical research, and regulatory authority among interns and PGs was found with interns possessing better knowledge.

Conclusion: It is concluded that regulatory authorities such as Board of Studies of various medical universities, Dental Council of India, and Medical Council of India must take necessary steps to increase the knowledge of drug development process among dental and medical professionals. Incorporation of this topic in educational curriculum in the initial stages of graduation and postgraduation would be beneficial.

Keywords: Awareness, clinical research, drug development process, good clinical practice, knowledge, regulatory authorities

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INTRODUCTION

Development of a new drug and its approval for marketing is a time-consuming (on an average 13 years) and a costly

process (costing 20–24 billion approximately). Drug development process involves preclinical studies and clinical trials^[1-3] (studies carried to prove that new drugs

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are safe and effective for human subjects)^[4] along with comparison of new drug with already marketed standard drug. Then, approval by regulatory authorities for marketing is required.^[5] Postregulatory approvals, new drugs are made available for clinical use of patients,^[4] and pharmaceutical companies need to recover their research and development costs. To create awareness on newly developed compounds, representatives of these pharmaceutical companies meet the prescribing professional with inventory of gadgets and presentation material to prove the superiority of formulation being marketed by them. They approach the physicians with results of clinical trial and highlighted charts and bar graphs along with the marketing skills.

Investigators conducting clinical trials are required to have knowledge of drug development process, principles, and methodology of clinical trials and should have International Conference on Harmonization good clinical practice (ICH-GCP) training.^[6] On the other hand, research is not considered important among medical professionals leading to poor performance.^[7,8] During graduation, medical and dental students are seldom trained to analyze the results of the various research studies. They are not required to conduct research as a part of their graduation curriculum. During internship, graduates concentrate on preparation for postgraduate (PG) entrance test. While some are able to join PG studies, rest get into practice getting no opportunity for understanding research and related development activities. Graduate and PGs play a key role in health-care delivery system for which health research is important.^[9]

With the above trends, it remains unclear how graduates will be able to analyze various published studies and the possible biasness in the conducted research, limitations of studies and possible variation due to geographic and demographic differences of tested subjects. Focus of medical fraternity on research at PG and super-specialization levels has been falling. This further gets narrowed with the falling standards of medical education.^[10] For the succession of health-care system, knowledge of clinical development of new chemical entity is vital among professionals.^[5]

Marketing representative presents the pharmacological merits of new drug and compares it with already marketed products. They emphasize on results of clinical trials representing statistical findings such as graphs and videos. With the above background of understanding and analytical capabilities of physician, newer products are probably sold based on the presentation and merits of peddling skills of the representative companies.

Most if not all the medium- to large-sized hospitals are being formed as a research entity. This gives them the advantage of saving on tax and increases profitability. Website of the Clinical Trials Registry in India^[11] was explored, and it was found that estimated <1% of hospitals and <10% of research centers are enrolled for clinical studies. This shows that there exists a gap in available infrastructure and actual research centers. Those who have not enrolled may have infrastructure to conduct trials but are not participating due to ignorance. This study focuses to understand and analyze the awareness of various aspects of drug development process among young medical and dental graduates and PGs.

METHODOLOGY

A cross-sectional study was carried from May 2015 to August 2015 among the internees (graduates) and PG students of a medical and a dental college in Punjab. A list of the interns and PGs was obtained from respective colleges, and all of them were approached at their convenient timings; volunteering professionals were included in the study, and a written consent was obtained from the participants.

A predesigned questionnaire was devised, based on previous research studies and in consultation with faculty members of the department of medical and dental sciences and research department. The Questionnaire was got prevalidated and the necessary modifications were incorporated into the final questionnaire. The questionnaire covered demographic information and questions on (1) drug development, (2) clinical research, (3) GCP, and (4) regulatory authorities.

Out of total 296 professionals volunteered, 256 professionals completed the study (response rate of 86.4%). Grossly incomplete feedbacks ($n = 5$) were excluded from the study. The final analysis covered 251 professionals. Interns were selected as graduates as they had completed their study period, and PGs were selected for being trained in their specialized field. Responses of participants were categorized to prefixed grades in reference to the previous study:^[6] <50% as poor, 51%–74% as average, and 75%–100% as good. Knowledge about drug development process was assessed as percentage of correct responses. It was assessed by scoring 1 to the correct response and 0 for incorrect response. The maximum score was 7 for clinical research and minimum being 0; the maximum score was 10 for drug development and minimum being 0; the maximum score was 4 for GCP and minimum being 0; the maximum score was 6 for regulatory authorities and

minimum being 0; total score was calculated in the end by valuating the answers.

Statistical analysis

The data were entered in Microsoft Excel spreadsheet and were presented using frequencies, mean, and value as appropriate. The intergroup comparison was done using Student's *t*-test. $P \leq 0.05$ was considered statistically significant. The statistical analysis was done using SPSS version 20, IBM SPSS Statistics for Windows, Version 20.0. IBM Corp., Armonk, NY, USA.

RESULTS

This study aimed to assess the knowledge and awareness about the most basic aspects of clinical research and drug development process among dental and medical interneers and PGs. Questionnaire was provided to all the eligible participants of dental college ($n = 110$) and medical college ($n = 186$). Of the above, 101 (40%) interneers and 150 (60%) PGs participated and completed the study questionnaire [Table 1].

Out of 251 professionals who participated, for the section on drug development, 10% scored average and 90% scored in poor response category, whereas for clinical research section, 42.8% of participants fell in the average category and 57.1% of participants in poor category. None of the participants scored "good" [Table 2]. Knowledge of GCP and regulatory authority was found to be poor for all of the professionals.

Knowledge of drug development

Overall, study participants had 27.7% knowledge about drug development and 21.9% and 23.5% about registration and processing of investigational new drug application, respectively. A very low percentage of participants, i.e., 19.9%, responded correctly for time period taken to develop a drug.

Knowledge of clinical research

It was found that knowledge of clinical trials among medical and dental professionals was 68.9%. Only 37.8% of study population responded correctly about purpose of clinical trials in drug development process. Only 42.6% of participants responded correctly about four phases of clinical trials [Table 3].

Knowledge of regulatory authorities

Only 33.9% ($n = 85$) of participants were aware about regulatory authorities i.e. DCGI (Drug Controller General of India), USFDA (United States Food Drug Administration), EMEA (European Medicines Evaluation

Table 1: Distribution of participants among both colleges

	Dental college	Medical college	Overall (%)
Interns	54	47	40.2
PGs	47	103	59.7
Male	15	79	37.4
Female	85	72	62.6

PGs=Postgraduates

Table 2: Proportion of participants with correct answers

	Good	Average	Poor
Drug development	-	10	90
Clinical research	-	42.8	57.1
Regulatory authority	-	-	100
Good clinical practices	-	-	100

Good: > 75% correct responses, Average: 51-74% correct responses, Poor: < 50% correct responses

Table 3: Knowledge of drug development and clinical research

Knowledge about	Correct (%)
Drug development process	
IND application stands for investigational new drug	56.2
Registration of IND application	21.9
Processing for IND	23.5
Phase of clinical trial before which IND number is applied	31.1
Advantages of IND	49.4
Phase of clinical trial after which NDA number is applied	19.1
Cost needed to develop a new drug	12.0
Knowledge of time span taken to develop a new drug	19.9
Knowledge of pharmacokinetics	23.5
Knowledge of CRF in clinical trial	20.3
Clinical research	
Definition of clinical trials	68.9
Purpose of clinical trials	37.8
Different phases of clinical trials	42.6
Preclinical studies	53.9
Purpose of blinding procedure in clinical trials	59.4
Types of blinding procedures done in clinical trials	39.4
Objectives of the Phase 1 clinical trials	36.9
Regulatory authorities	
Different regulatory drug approval authorities	33.9
FDA	31.1
Ethical codes for biomedical research	28.3
Corrective actions taken by regulatory authorities as a consequence of tragedies in clinical trials	38.6
Ethical guidelines entailed by Nuremberg Code for biomedical research on human subjects.	29.1
Schedule Y requirements for clinical trials in India	25.9
GCP	
Meaning of GCP	28.3
GCP as an efficacy guideline	21.5
ICH	13.1
Thirteen ICH-GCP principles	37.1

IND=Investigational new drug, CRF=Case Report Form, FDA=Food drug Administration, GCP=Good clinical practice, ICH=International Conference on Harmonization

Agency), MHRA (Medicines and Healthcare products Regulatory Agency) and TGA (Therapeutic Goods Administration). Knowledge on ethical codes among study participants was only 28.3%, and guidelines entailed by Nuremberg Code were known to 29.1% of participants.

Knowledge of good clinical practice

GCP is an efficacy guideline which has to be followed by each professional whether in private or government practice. Results showed that awareness about GCP was less than one-third (28.3%) [Table 3].

Differences between various segments of participants

There was no significant difference in knowledge levels of male and female participants except for knowledge on clinical research section where female participants fared significantly better than male participants.

Among the participants, 32.2% of interns and 24.6% of PGs presented with correct knowledge of drug development, 51.3% of interns and 44.5% of PGs were acquainted with knowledge of clinical research, 34.6% of interns and 28.5% of PGs were found to have precise knowledge of regulatory authorities, and 25.0% of interns and 24.8% of PGs were aware of GCP. The above differences were statistically significant ($P < 0.05$) for sections on drug development, clinical research, and regulatory authority with interns having significantly better knowledge.

Knowledge levels of the professionals for most of the sections were $<50\%$. Interns had significantly ($P < 0.05$) higher levels of knowledge for sections, namely drug development, clinical research, and regulatory authority. There was no statistically significant difference in knowledge for section on GCP [Table 4].

Overall, knowledge among professionals was limited to only 48.4% about clinical research, 27.7% about drug development, 25.0% for GCP, and 31.0% for regulatory authority. Comparing the knowledge levels of dental professionals with medical professionals, dental professionals were found to have higher knowledge for three of the four sections [Figure 1]. There was a statistically significant ($P < 0.05$) knowledge gap among the medical professionals and dental professionals about clinical research.

DISCUSSION

Table 4: Knowledge of study participants toward drug development, clinical research, good clinical practices, and regulatory authorities

Section	Groups	Knowledge score (%)	P
Drug development	Interns	32.2	0.00*
	PGs	24.6	
Clinical research	Interns	51.3	0.03*
	PGs	44.5	
Regulatory authority	Interns	34.6	0.02*
	PGs	28.5	
Good clinical practice	Interns	25.0	1.00
	PGs	24.8	

*Statistically significant at 0.05 levels. PGs=Postgraduates

It has been said that training in research activities during initial stage of career with mandatory assessment of research capabilities may translate into increased interest in research at postgraduation level.^[9] On review, medical and dental curriculum was found to cover only a few of the relevant topics covered in the 2nd year under pharmacology subject. Indian medical and dental education system does not include research methodology in syllabus at undergraduate level. These topics are covered to a partial extent with little emphasis on the subject and focusing more on examination-oriented teaching and study.^[6] Medical and Dental Council of India has made it compulsory for the PGs to attend conferences, give paper presentations, and engage in publication of articles.^[12] While physicians are the main and important part of any clinical trial and drug development process, literature review suggests that the knowledge and awareness among physicians are poor in our country. Ideally, practicing clinicians should be able to assess cost-effectiveness, risk-benefit, and quality of life with the use of drug, followed by informed decision to prescribe the drug and discover long-term benefits and side effects of drugs among different patient populations. The poor knowledge of drug development in professionals may be due lack of interest, little research in drug development in colleges, and research projects undertaken passively for formal completion of requirements of curriculum rather than active hunt into quality research.

An earlier study on drug research carried out by interns and PGs in India has also been found to be unsatisfactory as compared to developed countries.^[13] In one study, knowledge of qualified professional about drug development was found to be 32% among medical students^[14] which is similar to the finding of the present study.

Ethics are given prime importance in modern system of medicine. Various guidelines have been formulated

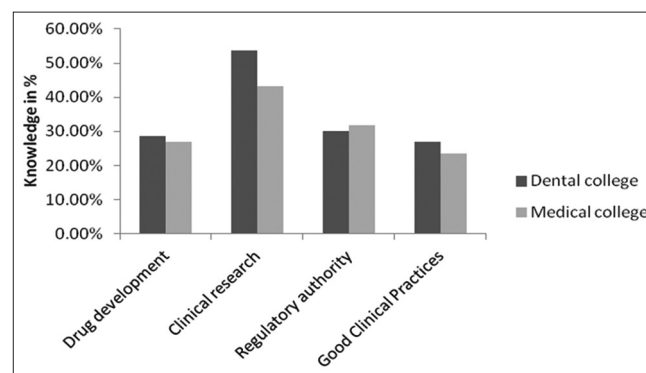


Figure 1: Knowledge of dental and medical professionals about drug development, clinical research, regulatory authorities, and good clinical practice

for protection of rights, safety, and well-being of trial participants. After World War II in 1947, the Nuremberg Code was formulated, and in 1964, the Declaration of Helsinki was formulated by the World Medical Association. It was considered as basis of ethical values to provide guidance and education about the safety and benefit of research subjects. It also bound physician to take important measures to safeguard the rights of human subjects involved in the research.^[15] About 28.3% of the participants responded appropriately about the ethical codes for biomedical research on human subjects, and these findings were in compliance with that of two different studies done in South India and North India among medical/dental students and faculty.^[16,17] Nearly 29.1% of the present study participants responded correctly about 10 guidelines entailed by Nuremberg Code, and similar observations were found among medical interns in Kathmandu^[18] and in doctors and nurses in Barbados.^[19]

In India, clinical trials are regulated by Schedule Y of the Drugs and Cosmetics Rules, 1945. Schedule Y provides the requirements and guidelines for import and/or manufacture of novel drugs for clinical trials or sale.^[19] Knowledge of Schedule Y requirements in India for clinical trials among study participants was found to be very poor (25.9%), and similar findings were revealed in different studies carried in Government Medical College and Hospital in East and South India.^[5,20] Lack of knowledge in professional toward regulatory authorities and their requirements may be due to the fact that Institutional Ethics Committees and other regulatory authorities are performing required tasks and are not taking any strict action if any misconduct of trials takes place. The major response of concern highlighted in our study was inadequate knowledge of Schedule Y requirements. The ICH-GCP is the standard for conducting a clinical trial. It deals with the design, conduct, and performance of a trial, and it also covers auditing, recording, analysis, and dissemination of the results of clinical trials.^[21] Guidelines have been formulated for protection of rights, safety, and well-being of trial participants. About 21.5% of professionals were aware about GCP as efficacy guideline, which was found to be similar to another studies carried out by different scientists for evaluating GCP and for assessing knowledge and perception regarding clinical trials among medical professionals.^[5,15] These results can testify the lacking curriculum in its focus on GCP for young professionals. An alarming low number of participants (13.1%) responded about ICH terminology with similar findings (12%) observed among health professionals in Karachi.^[15] About 37.1% of the participants had knowledge on ICH-GCP principles/guidelines, and similar results were observed in

previous studies conducted among health professionals in Saudi Arabia^[21] and in Uganda.^[22] These results can be attributed to the fact that curriculum has not been designed for GCP training among professionals.

In our study, 68.9% of the participants were found to be familiar with clinical research similar to the finding of a cross-sectional study carried out at a tertiary care hospital in Mumbai. This lower percentage knowledge of clinical research may be due to the absence of formal standardization of Clinical Research Training Program leading to knowledge gaps and misconceptions among professionals.^[23] In European country, only 23% of undergraduate professionals were involved in research projects.^[13,24]

Awareness on clinical research and drug development process was found to be low among interns and PGs of both medical and dental colleges. In India, 91% of interns were found to be unaware about research in their institution.^[9,25] Professionals in India are not much exposed to research at a phase of academic development.^[25,26] In our study, overall knowledge of clinical research was 48.4%, and of which, only 51.3% of interns were aware about clinical research. The present study postulates poor knowledge attributed to the inadequate curriculum, poor research interest, insufficient facilities, lack of funds and training, limited time period, inadequate infrastructure, etc., These findings were found to be similar with previous studies carried out by the different scientists.^[13,27,28]

CONCLUSION

From this study, it may be concluded that medical and dental professionals do not get an appropriate exposure to clinical research and drug development process during their graduation and postgraduation level. This has been clearly demonstrated in our study. Incorporation of basics of clinical research and drug development process in MBBS/BDS curriculum at graduation and postgraduation levels could be a beneficial step taken by Medical Council of India and Dental Council of India. Each institute should launch its training websites for continued education in recent areas of knowledge. Research training during period of residency can make them more enthusiastic for future research and practice. We must take the necessary steps to make widespread awareness among students about clinical research. Good motivation should be there for students to undertake clinical research and follow good practice guidelines. Medical and dental colleges should allocate mentors for research training and increasing interest of students toward research.

Limitations of the study

As data were collected based on self-information given by medical and dental students, therefore the possibility of reporting errors and recall biases could not be ruled out, and the opinion of nonresponders could also have affected the interpretation of the study. Data were collected from two colleges (one medical and one dental college) of Punjab, and as such, findings may not be representative of other colleges of the state.

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Conflicts of interest

There are no conflicts of interest.

REFERENCES

- Chhabra N, Bihani SG, Bhardwaj S. Introduction to various stages in process of drug development. *Int J Res Pharm Biomed Sci* 2012;3:38-49.
- Brodnicwicz T, Gryniewicz G. Preclinical drug development. *Acta Pol Pharm Drug Res* 2010;67:579-86.
- Singh RP, Singh SG. New drug development process. *Int J Res Pharm Biomed Sci* 2011;2:393-9.
- Bansal P, Gupta S, Christopher AF, Gupta V. Tragedies in clinical trials – A history wrapped up. *Int J Clin Pharmacol Toxicol* 2015;4:169-78.
- Choudhury S, Pradhan R, Dubey L, Barman L, Biswas T, Das M, *et al*. Knowledge and perception regarding clinical trials among doctors of government medical colleges: A questionnaire-based study. *Perspect Clin Res* 2016;7:94-9.
- Sharma KH, Jindal A. Low awareness of clinical research in India amongst final year medical professionals and physicians: Need for increased emphasis on clinical research in medical curriculum. *Med Educ* 2014;2:234-7.
- Mitwalli HA, Al Ghamdi KM, Moussa NA. Perceptions, attitudes, and practices towards research among resident physicians in training in Saudi Arabia. *East Mediterr Health J* 2014;20:99-104.
- Siemens DR, Punnen S, Wong J, Kanji N. A survey on the attitudes towards research in medical school. *BMC Med Educ* 2010;10:4.
- Sabzwari S, Kauser S, Khuwaja AK. Experiences, attitudes and barriers towards research amongst junior faculty of Pakistani medical universities. *BMC Med Educ* 2009;9:68.
- Batmanabane G. When angels fall...are we lowering the standards of medical education in India? *J Pharmacol Pharmacother* 2013;4:1-3.
- Available from: https://en.wikipedia.org/wiki/Clinical_trials_registry. [Last accessed on 2017 Sep 12].
- Giri PA, Bangal VB, Phalke DB. Knowledge, attitude and practices towards medical research amongst the postgraduate students of parvata institute of medical sciences university of central India. *J Family Med Prim Care* 2014;3:22-4.
- Pawar DB, Gawde SR, Marathe PA. Awareness about medical research among resident doctors in a tertiary care hospital: A cross-sectional survey. *Perspect Clin Res* 2012;3:57-61.
- Stanley AG, Jackson D, Barnett DB. The teaching of drug development to medical students: Collaboration between the pharmaceutical industry and medical school. *Br J Clin Pharmacol* 2005;59:464-74.
- Ahmed S, Khan S, Noushad S, Khan A. Good clinical practice; education as a necessitate for radiology. *Int J Endorsing Health Sci Res* 2014;2:62-5.
- Janakiram C, Gardens SJ. Knowledge, attitudes and practices related to healthcare ethics among medical and dental postgraduate students in South India. *Indian J Med Ethics* 2014;11:99-104.
- Mallela KK, Walia R, Tm CD, Das M, Sepolia S, Sethi P. Knowledge, attitudes and practice about research ethics among dental faculty in the North India. *J Int Oral Health* 2015;7:52-6.
- Aacharya RP, Yagya SL. Knowledge, attitude and practice of medical ethics among medical intern students in a medical college in Kathmandu. *Bangladesh J Bioeth* 2016;6:1-9.
- Harihara S, Jonnalagadda R, Walrond E, Moseley H. Knowledge, attitudes and practice of healthcare ethics and law among doctors and nurses in barbados. *BMC Med Ethics* 2006;7:E7.
- Hema N, Bhuvana K. Pharmacovigilance: The extent of awareness among the final year students, interns and postgraduates in a government teaching hospital. *J Clin Diagn Res* 2012;6:1248-53.
- Al-Nomay NS. Compliance with ICH-GCP guidelines among the Saudi health care professionals: Should Saudi Arabia conduct widespread ICH-GCP training? *J Public Health Dev Ctries* 2015;1:75-82.
- Ochieng J, Ecuru J, Nakwagala F, Kutuyabami P. Research site monitoring for compliance with ethics regulatory standards: Review of experience from Uganda. *BMC Med Ethics* 2013;14:23.
- Dhodi DK, Thakkar KB, Billa G, Khobragade AA, Sinha SR, Patel SB. Knowledge, attitude and practices of medical professionals and teachers towards clinical research in a tertiary care hospital in Mumbai – cross sectional survey. *J Contemp Med. Educ* 2013;1:238-44.
- Kolcica I, Polasek O, Mihalj H, Gombac E, Kraljevic V, Kraljevic I, *et al*. Research involvement, specialty choice, and emigration preferences of first year medical students in Croatia. *Croat Med J* 2005;46:88-95.
- Chaturvedi S, Aggarwal OP. Training interns in population-based research: Learners' feedback from 13 consecutive batches from a medical school in India. *Med Educ* 2001;35:585-9.
- Aslam F, Shakir M, Qayyum MA. Why medical students are crucial to the future of research in South Asia. *PLoS Med* 2005;2:e322.
- Alghamdi KM, Moussa NA, Alessa DS, Althimeen N, ALSaud AS. Perceptions, attitudes and practices toward research among senior medical professionals. *Saudi Pharm J* 2014;22:113-7.
- Budimir V, Cerjan-Letica G, Budimir J, Macan D. Knowledge, attitudes, and awareness of croatian dentists concerning patients' confidentiality and privacy. *J Dent Educ* 2013;77:370-6.